



PATENT
Customer No. 22,852
Attorney Docket No. 07580.0008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
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Satoshi YOSHIDA *et al.*) Group Art Unit: 1655
)
Application No.: 10/553,798) Examiner: C. Chen
)
Filed: October 18, 2005)
)
For: AGENT FOR INCREASING) Confirmation No.: 6122
GRANULOCYTE MACROPHAGE)
COLONY STIMULATING)
FACTOR)

**Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450**

Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

In reply to the final Office Action mailed June 15, 2007, and the Advisory Action mailed October 5, 2007, Applicant respectfully requests panel review of the twice rejected claims. A Notice of Appeal accompanies this request. In view of the concurrently filed petition for a one month extension of time, this reply is due October 15, 2007, and is timely filed.

No amendments are being filed with this Request. Applicant's remarks begin on page 2.

REMARKS

I. Status of the Claims

Applicant acknowledges with appreciation that the Office has entered the Amendment filed September 13, 2007. Claims 2 and 3 are under consideration.

II. Rejection Under 35 U.S.C. § 103(a)

The Office maintains its rejection of claims 2 and 3 under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,882,672 to Kojima et al. ("*Kojima*") in view of Nissen et al, Blood (1998) 72:2045-72 ("*Nissen*"). Final Office Action, page 3; Advisory Action, page 2. Applicant respectfully traverses this rejection.

"The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness." M.P.E.P. § 2142. The factual inquiries that the Office must take into account in reaching its conclusion were set forth by the Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Namely, the Office must "determine the scope and content of the prior art," "ascertain the differences between the claimed invention and the prior art," and "resolve the level of ordinary skill in the pertinent art." *Graham*, 383 U.S. at 17-18, 148 USPQ at 467. Various rationales can be used to support a finding of obviousness. 72 Fed. Reg. 57526, 57529 (Oct. 10, 2007). Nevertheless, the Supreme Court has emphasized that a finding of obviousness requires an explicit analysis of why the invention would have been obvious to one of ordinary skill in the art at the time the invention was made. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385, 1396 (2007). Thus, whatever the rationale relied upon, there still must be some logical, factual basis underlying the Office's position.

Here, the Office cites *Kojima* for its teaching of a composition comprising safflower (*carthamus tinctorius*), cucurbita seed, plantago, and lonciera. Final Office Action, page 3. It acknowledges that *Kojima* does not teach a composition comprising the recited amounts of the components of the composition. *Id.* And, it acknowledges that *Kojima* does not teach that the composition can be used in the recited methods of treating neutropenia or aplastic anemia. *Id.* at 4. Nevertheless, the Office alleges that:

one of ordinary skill in the art would reasonably expect that the referenced composition could be used to treat neutropenia or aplastic anemia based on [that] the claimed compounds can increase the resistance against a broad range of microorganisms, parasites (column 3, lines 7-8) through their effects in the immune system (column 1, lines 66-67).

Id. Apparently to support that allegation, it notes that *Nissen* teaches that GM-CSF can be used to increase granulocyte counts in neutropenia and in aplastic anemia. *Id.* From these teachings, the Office concludes that the ordinary artisan would have found it obvious to use the recited composition to treat neutropenia and aplastic anemia. *Id.*

Applicant respectfully submits that there is a gap in the logic the Office uses to reject the method claims and that neither the teachings of the references nor the general knowledge of the ordinary artisan fills that gap. The only possible connection between the two cited references is Applicant's own disclosure that the recited composition increases levels of GM-CSF in the blood. Absent that disclosure, there is no basis from which the ordinary artisan could derive either motivation to use the composition in the recited methods of treating aplastic anemia and neutropenia, or any reasonable expectation that the composition could be so used.

Respectfully, *Kojima* does not teach or suggest that its composition or the composition's components can be used to treat neutropenia or aplastic anemia, as claimed. *Kojima* also does not teach that its composition leads to an increase in GM-CSF levels. *Kojima* does not even mention GM-CSF. And although *Nissen* teaches that GM-CSF can be used to increase granulocyte counts in neutropenia and in aplastic anemia, that teaching exists in a vacuum in the absence of something linking the composition of *Kojima* to increases in GM-CSF in the blood.

The Office seems to imply that *Kojima*'s teaching of increased resistance to microorganisms necessarily implicates GM-CSF. But, it was well known to the ordinary artisan that increased resistance to microorganisms can be mediated by many different mechanisms that do not involve enhancement of GM-CSF levels or result in an increase in granulocytes. For example, most common antibiotics provide resistance to microorganisms by directly inhibiting or interfering with some aspect of the microorganism's biology. Nothing in *Kojima*, *Nissen*, or knowledge generally available to the ordinary artisan at the time the invention was made indicates that resistance to microorganisms is necessarily related to increases in GM-CSF. Therefore, without some showing of an effect of the composition on GM-CSF levels, the teachings of *Nissen* are completely irrelevant to whether the ordinary artisan would have found it obvious to prepare the composition as recited (the specific aspects of which also are not taught by *Kojima*) and use it to treat neutropenia or aplastic anemia, as claimed.

Applicant again respectfully submits that the Office has relied upon Applicant's disclosure that the recited composition increases GM-CSF in formulating its rejection. Such reliance, however, is impermissible. Instead, the Office must point to some

teaching *in the prior art or in the ordinary artisan's general knowledge* to provide a rationale for why the claims would have been obvious to the ordinary artisan at the time the invention was made. Absent a teaching that the composition increases levels of GM-CSF in the blood, there is no logical basis for utilizing the composition in methods of treating neutropenia or aplastic anemia, nor would there be any reasonable expectation that the composition would function in those methods.

Applicant respectfully submits that the Office has impermissibly relied upon Applicant's disclosure to provide the rationale upon which it relies in formulating its rejection under 35 U.S.C. § 103(a). For at least that reason, the Office has failed to carry its burden in establishing a *prima facie* case of obviousness. Applicant therefore respectfully requests that the Office withdraw the rejection.

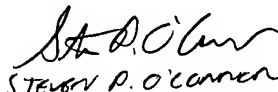
Conclusion

In view of the foregoing remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
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STEVEN P. O'CONNOR

By: REG. NO. 41,225 FOR

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Dated: October 15, 2007